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SUBJECT: TAIWAN TIFA FOLLOW UP - DRUGS - SHORT TERM
PROGRESS, LONG-TERM WORRIES

REF: TAIPEI 2570

Summary

1. As part of TIFA follow-up meetings, Deputy Assistant U.S. Trade Representative Eric Altbach and delegation discussed pharmaceutical issues with the Department of Health (DOH) and the Bureau of National Health Insurance (BNHI) as well as local representatives of U.S. pharmaceutical firms. These firms, while concerned about achieving the long-term goals of separating prescribing and dispensing (SPD) and actual transaction pricing (ATP), were pleased with progress they had made with DOH and BNHI in anticipation of the DAUSTR meetings. DOH agreed not to change the R-zone from the current 15% and eliminated therapeutic groupings of drugs. The DOH also agreed not to seek price cuts for several specific drugs. In the meeting with DOH, DAUSTR Altbach stressed the need to make the Price Volume Survey (PVS) more predictable, accurate, and transparent, and to consult with all stakeholders. DOH agreed to improve data collection in the future. Regarding the current PVS, Altbach urged DOH to apply the Merck Index 1982, as opposed to Merck Index 1984 as proposed by DOH. DOH noted that they were prepared to be flexible on this point. DAUSTR stressed the need to make meaningful progress on SPD and ATP and suggested additional discussions, via DVC, before the final PVS results are announced on October 1. AIT will follow up with DOH on DVC timing and other issues as well as continue to reiterate that real progress needs to be made under the TIFA process. Meaningful progress on ATP and SPD will be difficult. Other (non-pharmaceutical) issues discussed by delegation reported septel. End Summary.

US Industry sees some progress from TIFA dialogue

2. As a lead up to meeting with DOH, DAUSTR Altbach met with local representatives of US pharmaceutical firms. They stated that in anticipation of the TIFA follow up meetings, DOH had already met with them several times and had offered some concessions. They stated DOH had agreed not to change the R-zone from 15%, as opposed to an earlier suggested 8.5%. (The R-zone is the acceptable discount - expressed as

a percentage of the government reimbursement rate - which a hospital receives from a drug distributor.) They also noted DOH had agreed to eliminate therapeutic groupings of drugs for pricing purposes, and not to seek price cuts for several specific drugs. The patent-term for pricing purposes was still under discussion (reftel).

¶3. DOH previously announced that for the 5th PVS, the Merck Index 1984 would be used to determine whether or not to consider a drug on-patent for pricing purposes. The PVS study of two years ago, however, used the Merck Index 1980. Moving to the Merck Index 1984 would result in 2-years' loss of patent coverage for pricing purposes. After extensive discussions, DOH had told industry that they were considering a compromise and shifting to Merck Index 1983. Industry is still pushing for Merck Index 1982, to be consistent with the patent-term in prior surveys.

But industry still has plenty to worry about

¶4. While pleased with the progress made in talks with DOH in advance of the DAUSTR visit, industry continues to raise concerns about the PVS and its accuracy and transparency. Several industry representatives had raised concerns about the new "C-survey," which is an additional comparison of data reported by distributors and hospitals. Significant discrepancies are pulled for further investigation and referred to the Ministry of Justice. While most of the investigations seemed to involve local companies, several international firms stated that they also had one or two drugs on the list. Industry was concerned that they had not seen any criteria for inclusion in this survey. It is still sometimes not clear what data needs to be reported, they pointed out. It is also not clear what possible administrative or criminal penalties they might face, if any, as a result of this survey. One initiative that might

improve the accuracy of data collection, they suggested, was for DOH to mandate hospitals and drug suppliers use a standard contract that capture all payments surrounding the transaction to clarify the true cost hospitals pay for each drug.

¶5. Although generally pleased with the results of their consultations with DOH on the mechanics of the current PVS, industry is pessimistic about DOH reaching the long-term goals of separating prescribing and dispensing (SPD) and actual transaction pricing (ATP). They urged the USG to continue pushing DOH to make steps towards these goals. And although they were pleased DOH had decided not to pursue therapeutic grouping, they were still disappointed that DOH groups their off-patent brand-name drugs with generics for pricing purposes.

DOH wants to talk

¶6. After meeting with industry, Altbach and delegation met for three and a half hours and through lunch with Department of Health officials led by Vice Minister of Health Chen Shih-Chung and Bureau of National Health Insurance President Liu Chien-Hsiang. The meeting covered the full range of drug pricing issues - both immediate concerns over the current PVS as well as long-term goals of SPD and ATP. The discussions were friendly and open, and throughout the meeting, there were several requests for continued discussions at various levels. DOH officials emphasized that Vice Premier Tsai Ing-Wen had taken a personal interest in the TIFA pharmaceutical dialogue. (Note: Tsai told AIT/T Director on August 16 that she had met with DOH and that she had or shortly would also meet with industry representatives from the U.S., the EU and Japan. End note.)

The 5th Price Value Survey - striving for accuracy, transparency, predictability

¶7. DAUSTR expressed appreciation that DOH and BNHI had been actively engaged in consultations regarding the 5th PVS with

international pharmaceutical firms, stressing that the survey should be transparent, predictable, and gather as accurate data as possible. He urged DOH to continue to consult with stakeholders and also to clarify what data is required to be disclosed in the survey as well as to clarify what penalties can be imposed for incorrect reporting. He cited the "C-Survey" as an example. DOH officials reported that the "C-Survey" was initiated after the Vice Premier urged the Ministry of Justice to get involved in dealing with fraudulent reporting. DOH officials were uncertain what possible actions that the MOJ would take. DAUSTR urged continued consultation on C-survey implementation and how administrative and criminal penalties might be applied.

¶18. He suggested DOH could develop a standardized contract for hospitals and drug suppliers that included all relevant information and identified payments that could help increase both transparency and data accuracy. BNHI Vice President Lee stated that this was an excellent idea and that his office was currently developing such a contract. He stated that BNHI was serious about dealing with fraudulent and misleading reporting. One official stressed the difficulty of truly capturing all of the payments surrounding a transaction, noting that sometimes drug suppliers make payments into a separate entity as part of a transaction. The Taiwan side further requested that they be able to consult with the USG Health and Human Services Inspector General to study US efforts to investigate and prosecute false data reporting. Vice Minister Chen also reiterated the importance of this issue, noting that Vice Premier Tsai Ing-Wen had ordered DOH to study the issue of establishing what he described as a "fair transaction" environment and that he would be meeting soon with Taiwan's Fair Trade Commission to seek their help in improving transparency and accountability.

¶19. DAUSTR also urged the DOH to apply the principles of consistency and predictability in applying patent-definition for pricing purposes, stating that the USG viewed the Merck

1982 Index as being most consistent with past surveys since it applied the same patent-term. DOH officials stated that this issue was still under internal discussion.

¶10. Altbach also stressed the need to continue to take meaningful steps to move to SPD and ATP. DOH officials agreed that was also their goal, but that it would take time. They highlighted several initiatives currently planned or in place to move closer to this goal:

- requiring physicians to actually give their patients a copy of any prescription so that they would have the choice of filling it at any pharmacy.
- Auditing doctors every 3 months to insure that they are complying with the policy
- Requiring local pharmacies to legally register their ownership to increase the chance that they would separate from physicians
- start a lottery system whereby patients could use prescription receipts as lottery tickets. (Note: This sounds hokey, but a similar lottery based on general tax receipts is enormously popular in Taiwan. End note.)

Next Steps

¶11. AIT will follow-up with DOH/BNHI and with USTR to set up a DVC to review progress before the October 1 announcement of the PVS results. We will also further investigate the possibility of DOH officials meeting with our own HHS staff in Washington. We will also reiterate with DOH that while we were generally pleased with the dialogue to date, the USG will continue to look for real progress and real reforms as part of the TIFA process.

Comment:

¶12. The word has clearly gone out that the DOH needs to actively engage the USG in the TIFA process. They were prepared to talk about all aspects of their national health

care system, and made a real effort to work with industry in anticipation of Altbach's visit. Progress on a more transparent Price Value Survey, while welcome, is far from reaching the long term goal of eliminating the PVS and moving to SPD and ATP. DOH acknowledges that this will take considerable time.

¶13. Although far from perfect, Taiwan's National Health Insurance Program is inexpensive and accessible, and is one of the few popular programs of the current administration. Any actions that raise prices to users or radically change the system are likely to meet widespread political opposition. It would take a significant and surprising political commitment to implement these changes anytime soon. As a counterbalance to current political realities, however, the dramatically under-funded status of the program means reform will - eventually - be necessary. With its current level of financing, the program is unsustainable.

YOUNG